

Practitioner's Docket No. MPI02-202P1RNM

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:	George Mulligan et al.		
Application No.:	10/728,055	Group No.:	1642
Filed:	December 4, 2003	Examiner:	Reddig, Peter J.
For:	METHODS FOR THE IDENTIFICATION, ASSESSMENT, PREVENTION AND TREATMENT OF PATIENTS WITH PROTEASOME INHIBITION THERAPY		

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

**IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING  
INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed:

☒ Within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

**OR**

☐ *After* three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but *before* the mailing date of either:

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**CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\***

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

☒ deposited with the United States Postal Service in an envelope addressed to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**37 C.F.R. SECTION 1.8(a)**

**37 C.F.R. SECTION 1.10\***

☒ with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Address"  
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**TRANSMISSION**

☐ transmitted by facsimile to the Patent and Trademark Office (571-273-8300)

Signature

Sean Hunziker/Beverly Sotiropoulos

Date: June 7, 2007

(type or print name of person certifying)

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b). "Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

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- (1) a final action under Section 1.113,
- (2) a notice of allowance under Section 1.311, or
- (3) an action that otherwise closes prosecution in the application

whichever occurs first.

☐ Accompanying this transmittal is the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (\$180.00).

☐ Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

**OR**

☐ The information disclosure statement transmitted herewith is being filed *after* a final action under Section 1.113, or a notice of allowance under Section 1.311, whichever occurs first, but before, or simultaneously with, the payment of the issue fee.

☐ In accordance with the requirements of 37 C.F.R. Section 1.97(d):

A. ☐ Accompanying this transmittal is the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (\$180.00).

B. ☐ Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

C. ☐ No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

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**FEE PAYMENT**

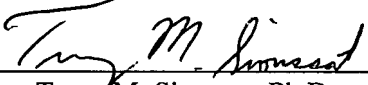
3. ☐ The fee due is set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c) (\$180.00).

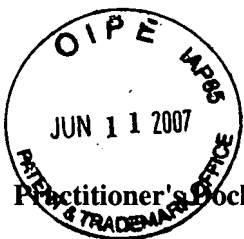
☒ Applicant believes no fee is due in connection with this submission.

	Fee due	\$0.00
<b>METHOD OF PAYMENT OF FEE</b>		
4. <input type="checkbox"/> Attached is a check in the amount of \$ _____.		
<input type="checkbox"/> Charge Account No. 501668 in the amount of	\$0.00	.

☐ A duplicate of this request is attached.

**If any additional fees are due, please charge Account 501668.**

<u>June 7, 2007</u>	<b>MILLENNIUM PHARMACEUTICALS, INC.</b> By <u></u> Tracy M. Sioussat, Ph.D. Registration No. 50,609 40 Landsdowne Street Cambridge, MA 02139 Telephone - 617-374-7679 Facsimile - 617-551-8820
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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

**List of Sections Forming Part of This Information Disclosure Statement**

The following sections are being submitted for this Information Disclosure Statement:

1. ☒ Preliminary Statements
2. ☒ Form PTO/SB/08B (1 page)
3. ☒ Copy of Listed Information Item(s) Accompanying This Statement
4. ☒ Identification of Person(s) Making This Information Disclosure Statement

**Section 1. Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty

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I hereby certify that, on the date shown below, this correspondence is being:

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to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

**Section 2. Copies of Listed Information Items Accompanying This Statement**

Legible copies of all relevant portions of items listed in Form PTO/SB/08B (substitute for Form PTO-1449) (references C10-C14) accompany this information statement.

June 7, 2007

MILLENNIUM PHARMACEUTICALS, INC.

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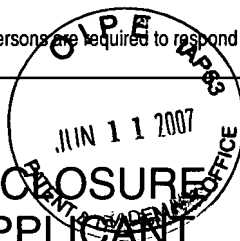
Please type a plus sign (+) inside this box → +

PTO/SB/08B (10-96)

Approved for use through 10/31/99. OMB 0654-0031

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Substitute for form 1449B/PTO				<b>Complete if Known</b>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  <i>(use as many sheets as necessary)</i>				Application Number	10/728,055
				Filing Date	December 4, 2003
				First Named Inventor	George Mulligan
				Group Art Unit	1642
				Examiner Name	Reddig, Peter J.
Sheet	1	of	1	Attorney Docket Number MPI02-202P1RNM	
<b>OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.			T <sup>2</sup>
	C10	Mulligan, George, et al., "Gene expression profiling and correlation with outcome in clinical trials of the proteasome inhibitor bortezomib," <i>Blood</i> , Vol. 109, No. 8 (April 15, 2007) pp 3177-3188			
	C11	"Affymetrix GeneChip Human Genome U95 Set HG-U95A," March 11, 2002 (sequence) Genbank, Bethesda, MD, USA: National Center for Biotechnology Information, Accession No. XP002293987			
	C12	An, W. G., et al., "Protease inhibitor-induced apoptosis: accumulation of wt p53, p21 <sup>WAF1/CIP1</sup> , and induction of apoptosis are independent markers of proteasome inhibition," <i>Leukemia</i> , Vol. 14, No. 7 (July 2000) pp 1276-1283			
	C13	Aghajanian, Carol, et al., "A phase I trial of the novel proteasome inhibitor PS341 in advanced solid tumor malignancies," <i>Clinical Cancer Research</i> , Vol. 8, No. 8 (August 2002) pp 2505-2511			
	C14	Zimmermann, Johann, et al., "Proteasome inhibitor induced gene expression profiles reveal overexpression of transcriptional regulators ATF3, GADD153 and MAD1," <i>Oncogene</i> , Vol. 19, No. 25 (June 2000) pp 2913-2920			
Examiner Signature				Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation design number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.